EXHIBIT K



Department of Health

ANDREW M. CUOMO Governor HOWARD A. ZUCKER, M.D., J.D. Commissioner

SALLY DRESLIN, M.S., R.N. Executive Deputy Commissioner

November 22, 2019

Dawn Mason, Executive Director of PPS Three Village Central School District 100 Suffolk Avenue Stony Brook, NY 11790

Re: Medical Exemption Request

Dear Ms. Mason:

I have reviewed the documentation submitted by Laura Bennett, MD with regard to the medical exemption request for the student with the date of birth of 2005. There are several points that can be made about this exemption:

 Autoimmune encephalitis is not a recognized contraindication for meningococcal conjugate (MenACWY) vaccine. The 2013 Infectious Diseases Society of America (IDSA) Clinical Practice Guideline for Vaccination of the Immunocompromised Host states the following with regards to patients with chronic inflammatory diseases, including immune-mediated and autoimmune diseases;

"Inactivated vaccines, including IIV, should be administered to patients with chronic inflammatory illness treated [...] or about to be treated [...] with immunosuppressive agents as for immunocompetent persons based on the CDC annual schedule.

[...]

Other recommended vaccines, including IIV and HepB vaccine, should not be withheld because of concerns about exacerbation of chronic immune-mediated or inflammatory illness."

The IDSA guidelines' accompanying table titled "Vaccination of Persons With Chronic Inflammatory Diseases on Immunosuppressive Medications" indicates that meningococcal conjugate vaccine should be given as per usual if patients are not current with recommendations for their risk and age categories.

The IDSA rated this as a strong recommendation with moderate-quality evidence, based on evidence from randomized control trials or exceptionally strong evidence from unbiased observational studies, and found that the desirable effects of offering inactivated vaccines such as MenACWY to persons with chronic inflammatory illnesses clearly outweigh undesirable effects.

Source: Rubin LG, Levin MG, Ljungman P, et al. 2013 IDSA Clinical Practice Guideline for Vaccination of the Immunocompromised Host, Clinical Infectious

Diseases, Volume 58, Issue 3, 1 February 2014, Pages e44–e100, https://doi.org/10.1093/cid/cit684.

- 2. Although moderate to severe <u>acute</u> illness is a precaution to vaccination, <u>chronic</u> Lyme or Bartonella diseases are not contraindications for MenACWY vaccine.
- 3. Postural Orthostatic Tachycardia Syndrome (POTS) is a condition in which affected patients' heart rates elevate and blood pressure drop when they quickly stand up after sitting or lying down, typically resulting in lightheadedness, blurred vision, and occasionally fainting. POTS is not a recognized contraindication for MenACWY vaccine, however it should be noted that the CDC and the American Academy of Pediatrics (AAP) both recommend that adolescents remain seated for 15 minutes following administration of any vaccine in order to reduce the risk of fainting.
- 4. Finally, while I empathize with this family for their loss, psychiatric issues in a sibling following meningococcal vaccine administration is not a contraindication for vaccination of other siblings.

It should be noted that although meningococcal disease is rare, the illness is often severe and can be deadly. In addition, persons with autoimmune diseases and other chronic infections are at high risk of severe infections and complications for meningococcal disease and other vaccine-preventable diseases if they are not vaccinated. For this reason, children with these conditions are specifically recommended to receive age-appropriate vaccines.

After evaluating the materials submitted for my review as well as available medical evidence, I find that the risks of not vaccinating this child with MenACWY vaccine outweigh the available evidence of potential risks for vaccination. Therefore, I recommend against accepting this medical exemption. If additional documentation should become available, please forward for my review.

If this child's healthcare provider has questions about the safety of vaccines in this child, then they can contact the CDC's Clinical Immunization Safety Assessment (CISA) project at CISAeval@cdc.gov to request a case evaluation. This service is provided free of charge. Additional information regarding CISA evaluations is available on the CDC's website at https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/clsa/evaluation.html. CISA evaluations might require up to three months. As such, if CISA agrees to evaluate the case then I would recommend a temporary medical exemption while the evaluation is underway and reassessment of the medical exemption following conclusion of the evaluation.

For more information on contraindication and precautions to vaccination please see the Advisory Committee on Immunization Practices' General Best Practice Guidelines for Immunization: Contraindications and Precautions online at https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.html.

Lastly, it should be noted that in making a determination on a medical exemption request, the school should seek the appropriate medical consultation (e.g., the school's medical director). The school may also request, as it has here, a recommendation from the New York State Department of Health (NYSDOH). However, after the appropriate consultation has occurred, "the principal or person in charge of a school" is responsible for making the final determination.

Sincerely,

Elizabeth Rausch-Phung, M.D., M.P.H Director, Bureau of Immunization